



## Statement of Lee, Shu-Wen

I, Lee, Shu-Wen, 79 years old, live at 6F, No. 86-39, Wen-Wu 2<sup>nd</sup> St., Cheng-Ging District, Kaoshiung, Taiwan.

1. I graduated from National Northwestern Medical Junior College, Lanzhou in 1945, which was promoted to be School of Medicine, Lanzhou University later. I fled from my hometown in Honan Province to Gangsu Province 60 years ago during Chinese-Japanese War. The Northwestern area was a vast territory with sparse population. There was no university in Northwestern provinces such as Gangsu, Qinghai, Xinjiang, Ningxia, Suiyuan and Nei Mongol due to the cultural lag. I felt great regret by not being able to obtain a Bachelor degree because I graduated from college before Lanzhou University was established.
2. I hereby make this statement to support my application of AIDS Recovery Drug (ARD) patent No. 10/089674 in the USA on April 2, 2002.
3. The ARD clinical trial was conducted by Dr. Chen in "Prevention & Control Institute of Venereal Disease and AIDS, Honan Province" in Shangcai County, Honan Province, People Republic of China, under the supervision of Director Chu, Xing-Ming. Execution of this project was also assisted by Lin-Fang, MD. Ph.D., Manager, Peijing Branch Office of Lee Pharmaceuticals, Hong Kong, and Dr. Chao. The test drug was formulated and provided by myself. The submitted information, forms, and statements were all true documents provided by Director Chu, Xing-Ming of "Prevention & Control Institute of Venereal Disease and AIDS, Honan Province" without dishonest advertising purpose. I further agree that I will accept the punishment of fine or imprisonment or both according to Article 18, Section 1001 of the US Code if this statement is false. I will also gratefully accept the fact that any falsehood found in the information provided herein might do harm to any patents which are under application process or have been proved.

With regards,

Affidavit : Lee, Shu-Wen      Signature : Shu-Wen Lee Date : December 3, 2003

## Summary

The symptoms and health status of 5 patients taking our specific AIDS treatments were significantly improved in 1 month of clinical trial. The range of CD4 cell number of these patients was 15~208 (mean 100). The symptoms and health status resulted from immunodeficiency were various among these 5 patients. Typical symptoms included fever, abdominal pain, cough, oral ulcer, herpes, skin itch, anorexia and weakness. Most of the symptoms were resolved after treatment and the typical fever among these 5 patients were under controlled. Hemoglobin levels were recovered to normal.

Traditional treatments are ineffective to manage the symptoms caused by immunodeficiency. Our results which specific AIDS treatments efficiently resolved the AIDS symptoms demonstrated that this treatment can specifically strengthen human immune response. However, the CD4 cell number and viral load were not significantly improved after 4 weeks of treatment. It is unlikely that the peripheral viral load of our patients can be decreased significantly (more than 10 fold) in short period (4~8 weeks) as observed in patients with cocktail treatment because our specific AIDS treatment is not anti-viral drugs which directly attack virus. The CD4 cell number would be decreased to be about 20 and the viral load would slightly increased after 4 weeks of treatment if patients did not take anti-viral drugs, according to the study reported in New England Journal of Medicine by Dr. Markowitz. In our study, the CD4 cell number was not decreased whereas the viral load was tended to be decreased after patients took specific AIDS treatment for 4 weeks. Among these patients, the viral load of patient A5 was decreased from 40800/ml to 2980/ml. The decreased amount was equal to the synergistic effect of 3 currently most effective anti-viral drugs. Besides, CD4 cell numbers in patients A1 and A4 were significantly increased.

What was more important was that not any toxic complications were observed in patients with specific AIDS treatment, whereas, common anti-viral drugs can induce various toxic complications. Therefore, except for anti-viral drugs, specific AIDS treatment was the only anti-AIDS treatment with confirmative effect which can significantly improve patients' life quality.

## 李叔文宣誓聲明書明

本人李叔文現年七十九歲，現住台灣省高雄市前金區文武二街八十六之三十九號六樓

一、本人於 1945 年畢業於蘭州國立西北醫專，於畢業同時學校奉命改制為蘭州大學醫學院，六十年前，適值中日作戰，家庭淪陷，隻身自家鄉河南省逃亡到甘肅省，因為西北地廣人稀，當時甘肅、青海、新疆、寧夏、綏遠、內蒙古等省，文化非常落後，沒有一所大學，以後當蘭州大學成立時，剛好我自醫專畢業，擦身而過，失之交臂，未能獲得學位，遺憾終生。

二、本人作此聲明以支持我在美國申請所發明的愛滋病特效藥 AIDS Recory Dry (ARD) 專利之申請案，該項申請美國編號：10/089674，申請日期 2002 年 4 月 2 日。

三、該 ARD 在中華人民共和國河南省上蔡縣的人體試驗，是由“河南省性病愛滋病防治研究所”主任朱新明監督下陳醫師執行，另由香港李氏大藥廠派遣該廠駐北京辦事處經理方玲醫學博士，及趙醫師協助進行，試驗用的藥物由本人李叔文負責調配供應。所檢送試驗的資料表格及文字敘述，純屬實情呈現，是上蔡縣性病愛滋病防治研究所主任朱新明提供者，沒有誇大不實宣傳行為。本人更願進一步聲明，如有故意不實之陳述，本人願接美國法典第 1001 節 18 條之規定，處以罰金或勞役或兩者併罰，如果此一送核資料有故意不實陳述，可能危及此一申請或任何已經核發予我之專利效力，本人均欣然接受，謹誓。

宣誓人：李叔文

簽名：李叔文

日期：03.12.20.

謹此

## 总 结

ARD

经过一个月的临床研究，5例病人在服用《抗AIDS特效治疗剂》后，症状和体征都有非常明显的改善。由于本次收取的病人CD4细胞数在208和15之间(平均100)，5位病人都有不同程度的因免疫缺陷而引起的症状和体征，典型的如发烧、腹疼、咳嗽、口腔溃疡、疱疹、皮肤瘙痒、食欲不振、乏力等。治疗后所有病人大部份症状和体征都消失，典型病人A5的高烧已得到控制，血红蛋白量都恢复到正常水平。

由于这些症状和体征是由于免疫缺陷而造成，一般治疗难以改善。而《抗AIDS特效治疗剂》能在短时间内改善这些症状和体征，说明其对人体免疫系统有独特的增强作用。虽然，在CD4细胞数和病毒载量的检测指标上，在治疗4星期后，并未见显著的改善。但由于《抗AIDS特效治疗剂》并非抗病毒药物，并不直接攻击病毒，因此，病毒载量不可能像鸡尾酒疗法的减少抗病毒数，在短期内(4-8周)把血液里的病毒数大大减少(10倍或以上)。根据Dr. Markowitz发表在New England Journal of Medicine上的文章，病人如没有用抗病毒药物进行治疗，4星期后CD4细胞数减少约20个，而病毒载量则略有增加，从我们的研究看，病人在服用抗AIDS特效治疗剂后，CD4细胞数在4星期后并未见减少，而病毒载量则出现下降趋势。其中，A5病人的病毒载量从40800/ml减低到2980/ml，减幅相当于目前最强的三种抗病毒药合用。而CD4细胞数方面，A1和A4病人也有较明显的提高。

更重要的是，病人服用《抗AIDS特效治疗剂》后，并未出现任何的毒副作用，而一般的抗病毒药物可对病人产生各种各样的毒副作用。因此，《抗AIDS特效治疗剂》是目前除抗病毒药外，唯一疗效确切的治疗爱滋病药物，可有效地改善病人的生活质量。